DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

HFC-35 m3198

Food and Drug Administration
New Orleans District
Southeast Region
4298 Elysian Fields Avenue
New Orleans, Louisiana 70122-3898

Telephone: 504-589-6341
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April 16, 1999

WARNING LETTER NO. 99-NOL-23

OVERNIGHT DELIVERY
FEDERAL EXPRESS

Mr. Charles G. Koch, CEO
Koch Industries, Inc.
4111 East 37th Street North
Wichita, Kansas 67220

Dear Mr. Koch:

An investigation of your medicated feed mill, Purina Mills, Inc. located at 223 West 63rd Street, Shreveport, Louisiana, conducted by Food and Drug Administration investigators on March 2-5, 1999, found significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds (Title 21, *Code Of Federal Regulations*, Part 225). Such deviations cause feeds being manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act.

Our inspection determined the following:

1. Failure to conduct adequate flushing or clean-out procedures which could result in unsafe contamination of the finished product. For example, on September 25, October 29, November 24, and December 4, 1998, medicated feeds containing Chlorotetracycline and Sulfamethazine (CTSM) were followed directly by dairy feed for lactating cows, Roughage Extender 12, [redacted] Also, medicated feeds containing Arsanilic Acid (AA) were followed directly by hog finishing feed, Hog Finisher LND BMD20, [redacted], on February 25, 1999, and by dairy feed, Roughage Extender 12, [redacted] on October 15, 1998.

2. Failure to follow your feed sequencing procedure, Quality Bulletin D20, "Drug Sequencing Requirements," in that medicated feeds containing CTSM were followed directly by dairy feed, Red Springs HFR DV, [redacted], on October 28, 1998 and December 23, 1998. Also, this same type of feed was preceded directly by dairy feed for lactating cows, Roughage Extender 12 [redacted], on November 24, 1998.

3. Failure to determine and correct the cause of medicated feeds not meeting assay specifications. Your firm did not follow your written procedure to investigate and to stop

distribution of all medicated feeds containing a drug for which an out of specification result was determined. For example, out of specification assay results were not investigated for the following samples of medicated feeds: [redacted] containing Chlorotetracycline, Sulfamethazine, and Penicillin on August 31 & October 22, 1998; and, [redacted] containing Chlorotetracycline and Sulfamethazine on March 2, April 3, May 21, August 18, September 15, 22, and December 2, 1998.

4. Failure to document analytical results for the third drug assay for the year [redacted] for medicated feed [redacted], containing Chlorotetracycline, Sulfamethazine and Penicillin. Please note, on the FDA-483 issued March 5, 1999, this observation, number 5, incorrectly identifies the time period as "...between 2/10/98 and 3/10/98." It should state that it is for the sample taken December 11, 1998.

Our inspection also determined your firm failed to label one turtle feed containing mammalian proteins with the required cautionary statement "Do not feed to cattle or other ruminants".

The above is not intended as an all-inclusive list of CGMP violations. As a manufacturer of medicated and non-medicated feeds, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law.

We acknowledge the receipt of a letter from Robert Fritz, Production Manager at the Shreveport, Louisiana facility. His letter, dated March 17, 1999, responds to observations listed on the FDA-483 issued March 5, 1999, at the close of our inspection. His letter will be reviewed and made a part of your firm's official file.

You should take prompt action to correct these CGMP violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these CGMP violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure, injunction and/or notice of opportunity for a hearing on a proposal to withdraw approval of your Medicated Feed License under Section 512(m)(4)(B)(ii) of the Act and Title 21, *Code of Federal Regulations*, Part 514.115(c)(2). This letter constitutes official notification under the law.). Based on the results of the March 2-5, 1999, inspection, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of medicated feeds are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drugs therein. This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies.

You should notify this office in writing, within fifteen (15) working days of the receipt of this letter, of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the CGMP violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to Nicole F. Hardin, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122, telephone number 504-589-7166.

Mr. Bob Broyles previously contacted the New Orleans District office to request a meeting to discuss FDA observations during the March 1999 inspection. This meeting is scheduled for May 4, 1999. Should you have any questions concerning the contents of this letter or the scheduled meeting, please contact Ms. Hardin.

Sincerely,

James E. Gamet
District Director
New Orleans District

Enclosure: FDA 483

cc: William W. Hanna, President, CEO
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